APR 30 2014
K133590

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510(K) SUMMARY

FOR

SOMATOM Pserspective

Submitted by:
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

Date Prepared: March 11, 2014

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. **General Information**
   Importer/Distributor:
   Siemens Medical Solutions USA, Inc.
   51 Valley Stream Parkway
   Malvern, PA 19355

   Establishment Registration Number:
   2240869

   Manufacturing Site:
   SIEMENS SHANGHAI, MEDICAL EQUIPMENT LTD.
   278 Zhou Zhu Rd
   Shanghai, CHINA 201318

   Establishment Registration Number:
   3003202425

2. **Contact Person:**
   Mrs. Kimberly Mangum
   Technical Specialist, Regulatory Affairs Submissions
   Siemens Medical Solutions, Inc. USA
   51 Valley Stream Parkway D02
   Malvern, PA 19355-1406
   Phone: (610) 448-1772 Fax: (610) 448-1778
   Email: kimberly.mangum@siemens.com

3. **Device Name and Classification**

Product Name:	SOMATOM Perspective
Propriety Trade Name:	SOMATOM Perspective
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750

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Device Class: Class II
Product Code: 90JAK

Legally Marketed Predicate Devices
Trade Name: SOMATOM Perspective
510(k)#: K113287
Clearance Date: May 23, 2012
Classification Name: System, X-Ray, Tomography, Computed
Classification Panel: Radiology
Classification Regulation: 21 CFR § 892.1750
Device Class: II
Product Code: 90JAK

Trade Name: SOMATOM Emotion 16
510(k)#: K050297
Clearance Date: March 01, 2005
Classification Name: System, X-Ray, Tomography, Computed
Classification Panel: Radiology
Classification Regulation: 21 CFR § 892.1750
Device Class: II
Product Code: 90JAK

4. Substantial Equivalence:
Siemens SOMATOM Perspective 16 and 32 slice configurations are substantially equivalent to the following medical devices in commercial distribution:

Predicate Device Name	*FDA Clearance Number*	*FDA Clearance Date*
SOMATOM Perspective	K113287	May 23, 2012
SOMATOM Emotion 16	K050297	March 01, 2005

5. Device Description:
The SOMATOM Perspective 16 and 32 slice configurations are whole body X-ray Computed Tomography Systems. The SOMATOM Perspective 16 and 32 slice configurations produce CT images in DICOM format, which can be used by post-processing applications commercially distributed by Siemens and other vendors.

The system software is a command-based program used for patient management, data management, X-ray scan control, image reconstruction, and image archive/evaluation. The new version of system software, syngo®

CT VC28 (SOMARIS/5 VC28) supports several new features which support more economical and energy efficient scanner operation.

6. **Summary of Technical Characteristics of the Subject Device as Compared with the Predicate Device:**
The SOMATOM Perspective 16 and 32 slice configurations are comparable in Indications for Use, material, functionality, technology, energy source, and are considered substantially equivalent to the predicate devices SOMATOM Perspective (K113287, clearance date May 23, 2012) and the SOMATOM Emotion 16 (K050297, clearance date March 01, 2005).

The SOMATOM Perspective 16 and 32 slice configurations are intended to produce whole body cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes taken at different angles. The imaging components (tube, collimator, detector, and DAS) are the same as the predicate devices.

The SOMATOM Perspective 16 and 32 slice configurations include the following new system features designed to allow more efficient system use:

- **eCockpit** - Software bundle designed to support more efficient system use
- **eStart** – Software option designed to extend the tube life by pre-warming the tube before a scan
- **eSleep** – Software option designed to save energy by stopping the gantry rotation during scan breaks

Additionally, the SOMATOM Perspective 16 and 32 slice configurations support the following acquisition method:

- **Single Source Dual Energy Acquisition** – Scanning and reconstruction of two spiral scans with different tube voltages (Dual Energy)

The intended use and fundamental scientific technology are similar to the predicate devices; therefore Siemens believes that they are substantially equivalent to the predicate devices.

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7. Nonclinical Testing:

The SOMATOM Perspective 16 and 32 slice configurations are designed to fulfill the requirements of following standards:

Recognition Number	Product Area	Title of Standard	Reference Number and Date	Publication Date	Standards Development Organization
5-40	General	Medical devices – Application of risk management to medical devices	14971 Second Edition 2007-03-01	08/20/2012	ISO
13-8	Software	Medical device software – Software life cycle processes	62304 First edition 2006-05	08/20/2012	IEC
5-41	General	Medical electrical equipment – Part 1-4: General requirements for safety – Collateral standard: Programmable electrical medical systems, edition 1.1	60601-1-4: 2000 Consol.Ed 1.1	09/08/2009	IEC
12-218	Radiology	Digital Imaging and Communications in Medicine (DICOM)	PS 3.1 – 3.18 (2008)	2008	NEMA
12-222	Radiology	Evaluation and routine testing in medical imaging departments - Part 3-5: Acceptance tests - Imaging performance of computed tomography X-ray equipment	61223-3-5 First edition 2004-08	03/18/2011	IEC
12-226	Radiology	Evaluation and routine testing in medical imaging departments - Part 2-6: Constancy tests - Imaging performance of computed tomography X-ray equipment	61223-2-6 Second Edition 2006-11	02/28/2011	IEC
12-250	Radiology	Medical electrical equipment - Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography - Ed. 3.0	60601-2-44 (2009):	09/09/2008	IEC
12-225	Radiology	Computed Tomography Dose Check	XR-25	03/18/2011	NEMA

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This submission contains performance data to demonstrate continued conformance with special controls for medical devices containing software. Non clinical tests (integration and functional) and phantom testing were conducted for the SOMATOM Perspective 16 and 32 slice configurations during product development. The modifications described in this Premarket Notification were supported with verification and validation testing.

The Risk analysis was completed and risk control implemented to mitigate identified hazards. The testing results supports that all the software specifications have met the acceptance criteria. Testing for verification and validation of the device was found acceptable to support the claims of substantial equivalence.

Software Documentation for a Moderate Level of Concern software per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005 is also included as part of this submission.

EMC/electrical safety was evaluated according to the IEC Standards. Siemens certify conformance to Voluntary Standards covering Electrical and Mechanical Safety. In conclusion, the identified risk of electrical hazards was mitigated and is substantially equivalent to the predicate device in terms of safety and effectiveness. All testing and validation has been completed.

8. **Indications for Use:**
The Siemens SOMATOM Perspective system is intended to produce cross sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes* taken at different angles.

In addition the SOMATOM Perspective is able to produce additional image planes and analysis results by executing optional post-processing features, which operate on DICOM images.

For cardiac imaging, which is an option on the system, a new reconstruction algorithm (iTRIM - Iterative Temporal Resolution Improvement Method) is used. iTRIM improves the temporal resolution of cardiac CT images compared to conventional cardiac CT image reconstruction. Actual results obtained with iTRIM can vary depending on the particular clinical situation.

The images and results delivered by the SOMATOM Perspective can be used by a trained physician as an aid in diagnosis.

(*spiral planes: the axial planes resulting from the continuous rotation of detectors and x-ray tube, and the simultaneous translation of the patient.)

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9. General Safety and Effectiveness Concerns:

The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device.

Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled during development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

10. Conclusion as to Substantial Equivalence

In summary, Siemens is of the opinion that the SOMATOM Perspective 16 and 32 slice configurations do not introduce any new potential safety risk and is substantially equivalent to and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 30, 2014

Siemens Medical Solutions USA, Inc.
Kimberly Mangum
51 Valley Stream Pkwy.
MALVERN PA 19355

Re: K133590/S002
Trade/Device Name: SOMATOM Perspective
Regulation Number: 21 CFR 892.1750
Regulation Name: System, X-Ray, Tomography, Computed
Regulatory Class: II
Product Code: JAK
Dated: March 25, 2014
Received: March 31, 2014

Dear Ms. Mangum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041

or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K133590

Device Name
SOMATOM Perspective

Indications for Use *(Describe)*

The Siemens SOMATOM Perspective system is intended to produce cross sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes* taken at different angles.

In addition the SOMATOM Perspective is able to produce additional image planes and analysis results by executing optional post-processing features, which operate on DICOM images.

For cardiac imaging, which is an option on the system, a new reconstruction algorithm (iTRIM - Iterative Temporal Resolution Improvement Method) is used. iTRIM improves the temporal resolution of cardiac CT images compared to conventional cardiac CT image reconstruction. Actual results obtained with iTRIM can vary depending on the particular clinical situation.

The images and results delivered by the SOMATOM Perspective can be used by a trained physician as an aid in diagnosis.
(*spiral planes: the axial planes resulting from the continuous rotation of detectors and x-ray tube, and the simultaneous translation of the patient.)

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*